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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,532	10/24/2003	Bruce Fletcher Johnson	130984-1	6876

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/691,532	JOHNSON ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/29/04; 10/15/04; and 11/17/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/29/04</u> . | 6) <input type="checkbox"/> Other: _____ |

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 10/15/04 wherein the specification and claims 32, 45, 46, 62, 63, 77, and 78 were amended.

Note: Claims 1-80 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed to compounds and uses thereof having the formula S-(L)_n-A wherein S is a signal, L is a linker, n is 0 or 1, and A is a peptide.

RESPONSE TO APPLICANT'S ELECTIONS

3. Applicant's election of Group VII directed to compounds and compositions of formula S-(L)_n-A that were not encompassed within the other Groups set forth in the restriction wherein A is the sequence TPP has been viewed as an election without traverse because Applicant did not point out the supposed errors in the restriction requirement. Thus, the restriction is deemed proper and is made FINAL. In addition, Applicant's election of the species wherein S is fluorescein, L is the linker KKGG, n is 1, Z is greater than 50, A is TPP, the metal chelating agent is TETA, and the disease being imaged is disease is acknowledged.

Initially, Applicant's species having formula S-(L)_n-A wherein A is TPP, L is KKGG, and S is fluorescein was search. Since prior art was not found to reject Applicant's claim, the search was extended to A is TPP, S is fluorescein, and L is

Art Unit: 1618

absent; still no prior art was found. Thus, the search was further extended to A is TPP. Since, not art was found. Group VII was modified to encompass compounds and compositions of formula S-(L)_n-A wherein A is TPP or MTTPPLT (for example, see claim 33).

Notes: Applicant is respectfully requested to delete all non-elected subject matter from the claims, address the 112 rejections below, and amend all of the method claims to include all the limitation of the allowable product (TPP and MTTPPLT) in order that the method claims may be rejoined to the allowable products.

112 SECOND PARAGRAPH REJECTIONS

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-80: The claims as written are ambiguous because independent claims 1 and 35 disclose the phrase 'S is a signal providing structure unit that provides a signal'. In particular, it is unclear what signal providing a structure that Applicant is referring to. Furthermore, since claims 2-34 and 36-80 depend upon independent claims 1 and 35, those claims are indefinite as well. In order to overcome the rejection, it is respectfully suggested that claim 1 be amended to disclose that S is a

Art Unit: 1618

signal selected from the group consisting of a luminescent dye, a radionuclide, a near infrared dye, a magnetically active isotope, a superparamagnetic particle, and a metal ion having a Z value greater than 50.

Claims 2, 36, 54, and 69: The claim as written is ambiguous because it is unclear what 'encapsulated species' Applicant is referring to which is compatible with the instant invention. In particular, if Applicant has identified the variable S as a signal providing structure that provides a signal wherein the signal is an encapsulated species, then it is unclear what species are useful with the instant invention. Applicant may overcome the rejection by identifying the specific encapsulated species that are compatible with the instant invention or deleting the phrase 'encapsulated species'.

Claims 3, 37, 55, and 70: The claims are ambiguous because of the phrase 'highly iodinated organic compounds chelates thereof', 'polymers containing at least one of the aforementioned components, and 'endohedral fullerenes containing at least one of the aforementioned'. In particular, it is unclear what organic compounds Applicant is referring to. Also, it is noted that the term 'highly' is a relative term, thus, the definition of the term 'highly' varies depending upon the reader. In addition, it is unclear what polymers and fullerenes Applicant is claiming to be compatible with the instant invention. Applicant may overcome this rejection by replacing 'highly iodinated organic compounds chelates thereof' with 'iodinated organic chelates' and deleting polymers containing at least one of the aforementioned components, and 'endohedral fullerenes containing at least one of the aforementioned' because some of the aforementioned

Art Unit: 1618

compounds in the claims are not necessarily polymer or endohedral fullerene forming compounds.

Claim 5: The claim as written is ambiguous because it is unclear what fluorescein, rhodamine, and Alexa derivatives Applicant is referring to that are compatible with the instant invention. Applicant may overcome the rejection by deleting the phrase 'derivative thereof'.

Claim 10: The claim as written is ambiguous because it is unclear what is a 'cye dye'. Please clarify and may the appropriate correction(s).

Claim 19: The claim as written is ambiguous because it is unclear what encapsulated species Applicant is referring to which is compatible to the instant invention.

Claims 21-25: The claims as written are ambiguous because it is unclear what organic radical Applicant is referring to. Applicant may overcome the rejection by incorporating the Markush of organic radicals of claim 26.

Claims 30, 43, 60, and 75: The claims are ambiguous because it is unclear what Applicant intends by the term 'CHXa'.

Claims 31, 44, 61, and 76: The claims as written are ambiguous because of the terms 'analog', 'derivatives', and 'variants'. In particular, it appears as if Applicant intends to encompass a multitude of species that are somehow different based on whether they are classified as 'lysine-glycine analogs', 'lysine-glycine derivatives', and 'lysine-glycine variants'.

Art Unit: 1618

Claims 33, 46, 63, and 78: The claim as written are ambiguous because it is unclear what variations of A are encompassed by Applicant's terminology of 'mixtures', 'fragments', 'fusion peptides', 'derivatives', 'variants', and 'homologues thereof'. In particular, it appears as if Applicant intends to encompass a multitude of species that are somehow different base on whether they are classified as mixtures', 'fragments', 'fusion peptides', 'derivatives', 'variants', and 'homologues thereof'. Applicant may overcome the rejection by deleting the terms and amending the claims to be selected from the allowable A groups (TPP and MTTPPLT).

Claims 34, 47, 64, and 79: The claims are ambiguous because of the term 'variants thereof'. It is unclear what variants Applicant is referring to. In order to overcome the rejection, it is respectfully suggested that the phrase be deleted because the search of Applicant's elected group is directed to TPP and MTTPPLT only, not variations thereof.

Claims 50 and 66: The claims as written are confusing because it is unclear what disease or disorder Applicant is referring to. Applicant may overcome the rejection by incorporating the disorders of claim 51 into the claim.

COMMENTS/NOTES

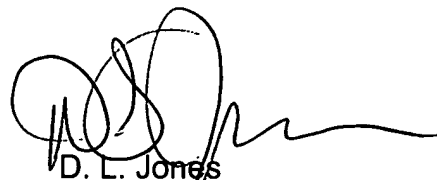
6. Applicant is respectfully requested to cancel the non-elected subject matter. In other words, the claims should be amended to include the allowable products (A is TPP or MTTPPLT).

Art Unit: 1618

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
Art Unit 1618

February 21, 2006